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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/511,481	02/23/2000	Gary J. Becker	97-998 US - DIV.	3875
7470	7590 07/01/2005		EXAM	INER
WHITE & CASE LLP PATENT DEPARTMENT			CHATTOPADHYAY, URMI	
1155 AVENUE OF THE AMERICAS			ART UNIT	PAPER NUMBER
NEW YORK	ζ, NY 10036		3738	
	•		DATE MAILED: 07/01/200	5

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	09/511,481	BECKER, GARY J.				
Office Action Summary	Examiner	Art Unit				
	Urmi Chattopadhyay	3738				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address						
Period for Reply  A SHORTENED STATUTORY PERIOD FO	R REPLY IS SET TO EXPIRE 3 I	MONTH(S) FROM				
THE MAILING DATE OF THIS COMMUNIC  - Extensions of time may be available under the provisions of after SIX (6) MONTHS from the mailing date of this community the period for reply specified above is less than thirty (30)  - If NO period for reply is specified above, the maximum stature to reply within the set or extended period for reply with Any reply received by the Office later than three months after earned patent term adjustment. See 37 CFR 1.704(b).	ATION.  37 CFR 1.136(a). In no event, however, may a ication.  days, a reply within the statutory minimum of the ory period will apply and will expire SIX (6) MC I, by statute, cause the application to become A	irty (30) days will be considered timely.  NTHS from the mailing date of this communication.  ABANDONED (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed	on <i>08 March 2005</i> .					
	)⊠ This action is non-final.					
3)☐ Since this application is in condition fo						
closed in accordance with the practice	under Ex parte Quayle, 1935 C.	D. 11, 453 O.G. 213.				
Disposition of Claims						
4) Claim(s) <u>21,22,25-29,31-34,37-54,62</u>	and 71-79 is/are pending in the a	pplication.				
4a) Of the above claim(s) is/are withdrawn from consideration.						
5)⊠ Claim(s) <u>62 and 71-79</u> is/are allowed.						
6)⊠ Claim(s) <u>21,22,25-29,31-34 and 37-5</u> 4	is/are rejected.					
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction	on and/or election requirement.					
Application Papers						
9)☐ The specification is objected to by the	Evaminer					
10)⊠ The drawing(s) filed on <u>05 January 20</u> 0		objected to by the Examiner				
Applicant may not request that any objecti						
Replacement drawing sheet(s) including the second to be s						
TI)	y the Examiner. Note the attache	of Office Action of form F 10-132.				
Priority under 35 U.S.C. § 119						
12)⊠ Acknowledgment is made of a claim fo	r foreign priority under 35 U.S.C.	§ 119(a)-(d) or (f).				
a)⊠ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority de		Application No. 00/004 400				
2. Certified copies of the priority documents have been received in Application No. <u>09/094,402</u> .						
	•	n received in this National Stage				
application from the Internation		A				
* See the attached detailed Office action	ior a list of the certified copies no	t received.				
Attachment(s)						
1) Notice of References Cited (PTO-892)	• —	Summary (PTO-413)				
2) Notice of Draftsperson's Patent Drawing Review (PTC		o(s)/Mail Date.				
3) Information Disclosure Statement(s) (PTO-1449 or Paper No(s)/Mail Date	O/SB/08) 5) Notice of 6) Other:	Informal Patent Application (PTO-152)				
U.S. Patent and Trademark Office PTOL-326 (Rev. 1-04)	Office Action Summary	Part of Paper No./Mail Date 20050624				

Art Unit: 3738

#### **DETAILED ACTION**

## Response to Amendment

1. The Supplemental Amendment filed 3/8/05 has been entered. The changes to the claims have been approved by the examiner. Claims 23, 24, 35, 36 and 55-61 have been canceled. All pending claims are being considered for further examination on the merits, which are claims 21, 22, 25-29, 31-34, 37-54, 62 and 71-79.

#### Allowable Subject Matter

- 2. Claims 62 and 71-79 are allowed.
- 3. The indicated allowability of claims 37-46 is withdrawn in view of the newly discovered reference(s) to Williams, Jr. (USPN 5,716,396) and Maeda et al. (USPN 5,507,767). Rejections based on the newly cited reference(s) follow.

#### Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 42 recites the limitations "first segment" in line 4 and "second filament" in line 6.

There is insufficient antecedent basis for these limitations in the claim. It appears that "first

Art Unit: 3738

segment" and "second filament" should be --first pattern-- and --second pattern--, respectively, and will so be interpreted for examination purposes.

## Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 7. Claims 47-54 rejected under 35 U.S.C. 102(e) as being anticipated by Williams, Jr. (USPN 5,716,396).

Williams, Jr. discloses a stent with all the elements of claim 47. See Figures 2 and 3 for a stent (21) consisting essentially of a generally tubular body with proximal and distal ends. See column 4, lines 40-50 for the body having a substantially continuous structure consisting essentially of a plurality of filament segments arranged to form a first repetitious pattern comprised of peaks (27) and valleys (27) and that advances substantially helically along the longitudinal axis. A plurality of connecting segments (28) connects peaks (27) to valleys (27). Because the peaks and valleys are welded to form joints, which provide as the connecting segments (28), the connecting segments and the peaks and valleys they connect are comprised of a continuous piece of material. See column 4, lines 54-55.

Claims 48 and 49, see Figure 2 and column 4, lines 45-48 for the peaks and valleys being of curvilinear filaments, and at least a portion of the first repetitious pattern being sinusoidal.

Art Unit: 3738

Claims 50 and 51, see Figures 2 and 3 for non-contiguous staggered connecting elements (28) forming a second repetitious helical pattern that is not parallel to the first pattern.

Claims 52 and 53, see Figure 2, column 4, lines 54-66 and column 6, lines 7-8 for the first and second repetitious helical patterns having opposing pitches (A, B) and sharing common filament segments.

Claim 54 is a product-by-process claim, and according to MPEP § 2113, this claim is not limited to the manipulations of the recited steps, only the structure implied by the steps. The patentability of a product does not depend on its method of production, but on the product itself. Therefore, how the stent is being manufactured is not further limiting the structure of the claimed stent.

#### Claim Rejections - 35 USC § 103

- 8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 9. Claims 21, 22, 25-29, 31-34 and 37-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams, Jr. in view of Maeda et al. (USPN 5,507,767).

Williams, Jr. discloses a stent with all the elements of claims 21 and 37, but is silent to first and second square-like tubular ends. See Figures 2 and 3 for a stent (21) having a main body with a length L, a longitudinal axis, a first introduction diameter and a second expanded diameter. See column 4, lines 40-50 for the main body having a plurality of contiguous

Art Unit: 3738

filaments arranged to form: (i) a first segment (having pitch angle A) propagating helically with respect to the longitudinal axis of the main body, the first segment having a repetitious pattern that comprises peaks (27) and valleys (27), and (ii) a second segment (having pitch angle B) also having a repetitious pattern and propagating helically. The first and second segments are joined together by connecting elements (28) that are integral portions of the first and second segments because they are the joints formed by welding. See Figure 2 for the segments crossing each other. The connecting elements, along with portions of the first segment form the second segment, wherein pitch angle B of the second segment is less than pitch angle A of the first segment. See column 4, lines 57-60. Maeda et al. teaches having a stent include first and second square-like tubular ends in order for the final stent to have a tubular shape in which the ends of the tube are substantially perpendicular to the axis of the stent. See Figure 1 and column 3, lines 43-50. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Maeda et al. to have the stent include end sections (claim 37) in the form of first and second square-like tubular ends (claims 21, 44 and 46), in order for the final stent to have a tubular shape in which the ends of the tube are substantially perpendicular to the axis of the stent. The end sections will have equal lengths less than the length L of the body of the stent (claim 45). In creating the square-like tubular ends, wire sections of different lengths are used and form varying amplitudes (claims 33 and 43). The first and second repetitious helical patterns will start and end between the end sections (claims 38 and 39).

Claim 22, see Figure 2 and column 4, lines 57-66 for first and second segments having different pitches.

Art Unit: 3738

Claim 25, see Figures 2 and 3 for the pattern of the first segment being distinct from the pattern of the second segment.

Claims 26 and 27, see column 7, lines 28-47 for the stent being manufactured from self-expanding and plastically deformable materials.

Claims 28 and 29, see Figures 2 and 3 for the circumferential dimension being parallel to the circumference of the stent and the total filament length of first and second segments being longer than the length L of the body.

Claims 31 and 32 are product-by-process claims, and according to MPEP § 2113, these claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. The patentability of a product does not depend on its method of production, but on the product itself. Therefore, how the stent is being manufactured is not further limiting the structure of the claimed stent.

Claim 34, see Figure 2 and column 4, lines 46-48 for the repetitious pattern being generally sinusoidal.

Claim 40, compare Figure 3 to Figure 2 for the first and second patterns circumferentially expanding when the stent (21) is expanded.

Claim 41, see Figure 2 for the length of the filament segments comprising the first repeating helical pattern is greater than L and the filament segments comprising the second repeating helical pattern is greater than L.

Claim 42, see Figure 2 for the total filament length of the filament segments of the first pattern being greater than  $L_{hell}$  and the total filament length of the filament segments of the second pattern being greater than  $L_{hell}$ .

Art Unit: 3738

# Response to Arguments

10. Applicant's arguments with respect to claims 21, 22, 25-29, 31-34 and 37-54 have been considered but are most in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached on Tuesday-Thursday 10:00am - 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Urmi Chattopadhyay

Art Unit 3738

David J. Isabella Primary Examiner